

§ 341.76

three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(ii) *For products containing menthol identified in § 341.14(b)(2) in a suitable ointment vehicle.* The product contains 2.6 to 2.8 percent menthol. “[bullet] see important warnings under ‘When using this product’ ” [appears as the first statement under the heading “Directions” and is highlighted in bold type] [bullet] adults and children 2 years and older: [bullet] rub on the throat and chest in a thick layer [bullet] cover with a warm, dry cloth if desired [bullet] clothing should be loose about throat and chest to help vapors reach the nose and mouth [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

* * * * *

(iv) *For products containing camphor identified in § 341.14(b)(1) for steam inhalation use.* The product contains 6.2 percent camphor. “[bullet] see important warnings under ‘When using this product’ ” [appears as the first statement under the heading “Directions” and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1½ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer’s directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water in the vaporizer and follow manufacturer’s directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

(v) *For products containing menthol identified in § 341.14(b)(2) for steam inhalation use.* The product contains 3.2 percent menthol. “[bullet] see important warnings under ‘When using this product’ ” [appears as the first statement under the heading “Directions” and is highlighted in bold type] [bullet] adults and children 2 years and older: (select one of the following, as appropriate: *For products formulated to be added directly to cold water inside a hot steam vaporizer.* [bullet] use 1 tablespoonful of solution for each quart of water or 1½ teaspoonsful of solution for each pint of water [bullet] add solution directly to cold water only in a hot steam vaporizer [bullet] follow manufacturer’s directions for using vaporizer or *For products formulated to be placed in the medication chamber of a hot steam vaporizer.* [bullet] place water

21 CFR Ch. I (4–1–02 Edition)

in the vaporizer and follow manufacturer’s directions for using vaporizer [bullet] place solution in the medication chamber only) [bullet] breathe in the medicated vapors [bullet] use up to three times daily or as directed by a doctor [bullet] children under 2 years of age: Ask a doctor.

* * * * *

§ 341.76 Labeling of bronchodilator drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a “bronchodilator.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the phrase listed in paragraph (b)(1) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) “For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.”

(2) In addition to the required information identified in paragraph (b)(1) of this section, the labeling of the product may contain one or more of the following statements:

(i) “For the” (select one of the following: “temporary relief” or “symptomatic control”) “of bronchial asthma.”

(ii) “Eases breathing for asthma patients” (which may be followed by: “by reducing spasms of bronchial muscles”).

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) “Do not use this product unless a diagnosis of asthma has been made by a doctor.”

(2) “Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.”

(3) “Do not use this product if you have ever been hospitalized for asthma or if you are taking any prescription drug for asthma unless directed by a doctor.”

(4) *Drug interaction precaution.* “Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson’s disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.”

(5) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racepinephrine hydrochloride identified in § 341.16 (a), (b), (c), and (f).* (i) “Do not continue to use this product, but seek medical assistance immediately if symptoms are not relieved within 1 hour or become worse.”

(ii) “Some users of this product may experience nervousness, tremor, sleeplessness, nausea, and loss of appetite. If these symptoms persist or become worse, consult your doctor.”

(6) *For products containing epinephrine, epinephrine bitartrate, or racepinephrine hydrochloride identified in § 341.16 (d), (e), and (g).* (i) “Do not use this product more frequently or at higher doses than recommended unless directed by a doctor. [first sentence in boldface type] Excessive use may cause nervousness and rapid heart beat, and, possibly, adverse effects on the heart.”

(ii) “Do not continue to use this product, but seek medical assistance immediately if symptoms are not relieved within 20 minutes or become worse.” [sentence in boldface type]

(iii) *For products intended for use in a hand-held rubber bulb nebulizer.* “Do not use this product if it is brown in color or cloudy.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing ephedrine, ephedrine hydrochloride, ephedrine sulfate, or racepinephrine hydrochloride identified in § 341.16 (a), (b), (c), and (f).* Adults and children 12 years of age and over: Oral dosage is 12.5 to 25 milligrams every 4 hours, not to exceed 150 milligrams in 24 hours, or as directed

by a doctor. Do not exceed recommended dose unless directed by a doctor. Children under 12 years of age: Consult a doctor.

(2) *For products containing epinephrine, epinephrine bitartrate, and racepinephrine hydrochloride identified in § 341.16(d), (e), and (g) for use in a hand-held rubber bulb nebulizer.* The ingredient is used in an aqueous solution at a concentration equivalent to 1 percent epinephrine. Inhalation dosage for adults, children 12 years of age and over, and children 4 to under 12 years of age: 1 to 3 inhalations not more often than every 3 hours. The use of this product by children should be supervised by an adult. Children under 4 years of age: Consult a doctor.

(Collection of information requirement approved by the Office of Management and Budget under control number 0910-0237)

[51 FR 35339, Oct. 2, 1986, as amended at 52 FR 7126, Mar. 9, 1987; 52 FR 7830, Mar. 13, 1987; 53 FR 35810, Sept. 15, 1988; 58 FR 54242, Oct. 20, 1993; 61 FR 25146, May 20, 1996; 62 FR 9684, Mar. 4, 1997; 64 FR 13295, Mar. 17, 1999]

§ 341.78 Labeling of expectorant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “expectorant.”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the following: “Helps loosen phlegm (mucus) and thin bronchial secretions to” (select one or more of the following: “rid the bronchial passageways of bothersome mucus,” “drain bronchial tubes,” and “make coughs more productive”). Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings, under the heading “Warnings”: